



5/14/97
efj

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1800
Telephone: 612-334-4100

PURGED

June 12, 1997

cc: HFI-35/FOI Staff
DWA

WARNING LETTER

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Refer to MIN 97-47

Mr. Cliff L. Hagen
President & General Manager
Cass Clay Creamery, Inc.
1220 Main Ave.
Fargo, North Dakota 58108-2947

Dear Mr. Hagen,

During an inspection of your firm on September 27 through October 3, 1996, FDA Investigators collected a sample (sample # 96-719-000) of cheddar cheese from eight barrels at your Tuttle, ND facility. FDA analysis of the sample found sulfamethazine (SMZ) in the cheese.

Cheese containing sulfamethazine is adulterated within the meaning of 402(a)(2)(D) of the Food, Drug, and Cosmetic Act (the Act) in that it contains a new animal drug which is unsafe within the meaning of 21 U.S.C. 360b since no approval of an application filed pursuant to 21 U.S.C. 360b(b) is in effect with respect to the use and intended use of such drug in lactating dairy cattle, which resulted in the presence of sulfamethazine in the cheese. Simply stated, the granular cheese curds represented by sample #96-719-000 are adulterated under Section 402(a)(2)(D) of the Act because they were found to contain sulfamethazine, a new animal drug for which there is no established tolerance that authorizes residues of this drug in cheese products.

The inspection found that your firm manufactured the sampled cheese from gallons (pounds) of whole milk that was delivered on September 9, 1996 to Cass Clay's transfer station in Jamestown, ND and subsequently transported to

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testing of the milk found that it contained a sulfa drug residue and they refused the shipment on September 10, 1996. The raw milk was returned to Cass Clay's Tuttle, ND facility on September 11, 1996. Analysis by the _____ verified the presence of a sulfa drug residue in milk from one of your producers, _____ who supplied milk for the suspect load. Your firm manufactured cheddar cheese from this milk on September 11, 1996.

Cass Clay was aware that the raw milk used in producing the cheese tested positive for the presence of a sulfa drug residue. Milk from the _____ farm was tested (using _____ on September 24, 1996 and found to contain a sulfa drug residue.

The Food and Drug Administration conducted another inspection of your cheese manufacturing firm on March 10, 19 & 25, 1997. A sample (sample #97-743-171) was collected of granular cheese product manufactured on January 24, 1997.

Analysis found it to be contaminated with oxytetracycline. The granular cheese curds represented by sample #97-743-171 are adulterated under Section 402(a)(2)(D) of the Act in that they contain oxytetracycline, an animal drug for which there is no established tolerance that authorizes residues of this drug in cheese products.

During the inspection of your facility, the investigator collected information which demonstrates that you were aware that the raw milk used in the manufacture of this cheese product was contaminated with oxytetracycline.

The Food and Drug Administration forbids the use of such contaminated raw milk as an ingredient in manufacture of cheese products.

This letter is not meant to be an all-inclusive listing of the deficient conditions and practices at your facilities. As president of Cass Clay Creamery, Inc. you are ultimately responsible for ensuring that all of your food manufacturing operations are operating in compliance with the Federal Food, Drug, and Cosmetic Act and associated regulations.

We request that you notify this office in writing within 15 working days of your receipt of this letter describing the measures you intend to take to correct the cited violations. If the corrections cannot be completed within 15 days, state the reason for the delay and the time within which the corrections will be completed.


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You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure and/or injunction, without further notice.

Your reply should be directed to Howard E. Manresa, Compliance Officer, Food and Drug Administration, 240 Hennepin Avenue, Minneapolis, MN 55401. Mr. Manresa may be reached at (612)334-4100 ext. 156.

Sincerely,



James I. Roberts
Acting Director
Minneapolis District

HEM